MAY 2 3 2003

510K(k) SUMMARY

K030592

SUBMITTER:	**Gambro Renal Products 10810 West Collins Avenue Lakewood, CO 80215 (303) 231-5075**
DATE PREPARED:	**February 19th 2002**
DEVICE NAME:	**Gambro POLYFLUX 140H, 170H and 210H Capillary Dialyzer/Filter Labeled for Single Use**
CLASSIFICATION NAMES:	**High Permeability Hemodialyzer / Hemofilter**
PREDICATE DEVICE:	**Gambro POLYFLUX 14S, 17S & 21S Hemodialyzers/Filters Labeled for Single Use & the Gambro GFS PLUS 20**

Device Description:

Gambro POLYFLUX 140H, 170H & 210H Capillary Dialyzers/Filters

The Gambro POLYFLUX 140H, 170H and 210H Capillary Dialyzers/Filters labeled for single use have the same design, materials, intended use and function as other hemodialyzers/filters currently marketed in the United States.

These devices are intended for use in hemodialysis for the treatment of acute and chronic renal failure. They may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in this device is polyarylethersulfone (PES) which is identical to the membrane utilized in the Gambro POLYFLUX 14S, 17S and 21S Hemodialyzers /filters labeled for single use which have been previously cleared for marketing in the United States under 510K Notifications (K982414). A copy of this clearance letter is included in Section X. D of this Notification.

Blood enters a blood inlet port where it is distributed to the hollow fibers. Each hollow fiber has an inner diameter of approximately 200 microns (hollow fiber internal diameter) and a wall thickness of 50 microns. The number of hollow fibers in each hemodialyzer / filter is 7,500 for the POLYFLUX 140H, 9,300 for the POLYFLUX 170H, and 12,000 for the POLYFLUX 210H. This effective membrane length is 270 mm for the POLYFLUX 140H, 170H and 210H. The effective membrane surface area is 1.4 square meters for the POLYFLUX 140H, 1.7 square meters for the 170H and 2.1 square meters for the 210H. The housing and end caps of this hemodialyzer / filter are made of polycarbonate. The design and incorporation of the silicone header gasket is the same as previously approved for the Gambro GFS Plus Hemodialyzers / Filters(K902481). The

fibers used in the Gambro POLYFLUX 140H, 170H and 210H are of the same composition as those previously approved for the Gambro POLYFLUX S Hemodialyzers / Filters labeled for single use (K982414).

The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port. By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along with certain lower and middle molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the countercurrent flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port. Schematic drawings of Gambro POLYFLUX 140H, 170H and 210H Capillary Dialyzers / Filters are included in this Section.

Predicate Devices:

The Gambro POLYFLUX 140H, 170H and 210H, Capillary Dialyzers / Filters labeled for single use have the same design, materials, component parts, intended use and function as other Gambro Hemodialyzers / Filters currently marketed in the United States. These dialyzers have been cleared for marketing / sale under 510K Notification K982414 for the Polyflux 14S, 17S & 21S and under 510K Notification K902481 for GFS Plus 20. The predicate and the proposed devices, incorporate identical membranes (Polyflux 14S, 17S & 21S) and other blood and non-blood contact materials as well as a silicone O-Ring which is not incorporated into the Polyflux S, but is incorporated into the GFS Plus 20. The Polyflux H dialyzers are therefore considered to be substantially equivalent to the listed predicate devices. The intended uses for the proposed and predicate devices are also the same, hemodialyzers indicated for hemodialysis for the treatment of acute and chronic renal failure.

Intended Use:

POLYFLUX H Indications:

The capillary dialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatments of chronic or acute renal failure.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent to the predicate devices. Both the proposed and predicate devices use the same hollow fiber membrane and other blood and non-blood contact materials. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material and are steam sterilized.

Summary of Non-Clinical Tests:

In vitro performance testing was performed to establish and compare performance characteristics to the predicate devices.

Conclusions:

Testing performed on the Gambro POLYFLUX H Capillary Dialyzers/Filters indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro performance data are included in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Jeffrey R. Shideman, Ph.D.
Director, Therapy Group Americas
Gambro Corporate Research
Gambro® Renal Products
10810 West Collins Avenue
LAKEWOOD CO 80215

Re: K030592
Trade/Device Name: Gambro Polyflux, 140H, 170H and 210H Capillary Dialyzers/Filters
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: February 19, 2003
Received: February 25, 2003

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF *KNOWN*): *Not yet assigned*

DEVICE NAME: _Gambro Polyflux 140H, 170H and 210H Capillary Dialyzer/Filter for Single Use

INDICATIONS FOR USE:

POLYFLUX H Indications:

The capillary dialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatments of chronic or acute renal failure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (**ODE**)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030592